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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANIEL ALROY

Appeal 2009-001920
Application 09/871,560
Technology Center 1600

Decided: September 1, 2009

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of identifying brain loci of neural correlates of a particular elementary mental state. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

Statement of the Case

The Claim

Claim 6 is on appeal. Claim 6 reads as follows:

6. A method for identifying brain loci of neural correlates of a particular elementary mental state, such as any innate submodality element of sensation, comprising the steps of:

(1) establishing correspondence between said submodality element of sensation and the external stimulus that normally elicits it, and then with a voluntary behavioral response, thus establish correspondence between said stimulus and said response, so that said behavioral response following said stimulus signifies the presence of the said element of sensation, and the absence of said behavioral response signifies the absence of said element of sensation;

(2) detecting, immediately following said external stimulus and said corresponding behavioral response, brain loci that manifest transient increased activation;

(3) identifying, among the said brain loci that manifested increased activation, activation in response to said stimulus, those whose inactivation selectively eliminates said behavioral response to said external stimulus, without eliminating behavioral responses to external stimuli that induce other elements of sensation within the same submodality.

The prior art

The Examiner does not rely upon any evidence.

The issues

A. The Examiner rejected claim 6 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement (Ans. 3-7).

B. The Examiner rejected claim 6 under U.S.C. § 112, first paragraph as lacking enablement (Ans. 7-10).

A. *35 U.S.C. § 112, first paragraph - written description requirement*

The Examiner finds that steps 1, 2, and 3 lack descriptive support in the Specification (*see* Ans. 4-6). For step 1, the Examiner finds that “the cited pages in the [S]pecification do not disclose a step of establishing correspondence in the context of the claimed method” (Ans. 4). For step 2, the Examiner finds that “[n]one of these citations describe an immediate detection of brain loci after performing step 1” (Ans. 5). For step 3, the Examiner finds that “the cited pages in the [S]pecification do not disclose identifying brain loci that activated in response to an external stimulus whose inactivation would eliminate a behavior response to the external stimulus” (Ans. 5-6).

Appellant contends that

Regarding New Matter Rejection. The discussion below of the enablement requirement and the Trivedi patent indicates that the Examiner misconstrued the present Specification in several crucial respects. Such misconstruction severed the connection between the Specification and the claim, contributing to an appearance that the claim is new matter. In addition, Applicant now understands that alternative wording, or lack of strict synonymy, can be grounds for new matter rejection. Such formulation flaws can generally be amended. Applicant would have amended the non-compliant language of the claim had the Examiner pointed out the non-compliant claim elements

(App. Br. 9).

In view of these conflicting positions, we frame the written description issue before us as follows:

Did the Examiner err in finding that the disclosure of the Specification failed to demonstrate possession and descriptive support for steps 1-3 of claim 6?

Findings of Fact (FF)

1. Claim 6 is drawn to a “method for identifying brain loci of neural correlates of a particular elementary mental state” (Claim 6).
2. The Specification teaches that “[i]n identifying the correlates of innate fear, for example, conditioned fear cues should be minimized, and the stimulus employed should evoke an innate response, such as abrupt loud noise or smell of cats” (Spec. 29).
3. The Specification teaches that “[e]lementary mental states are innate, evoked in the brain, and other than intensity and duration, have no internal constituents. The taste sensations of sweet, salty, sour, and bitter are innate” (Spec. 8).
4. Claim 6 requires a first step of “establishing correspondence between said submodality element of sensation and the external stimulus that normally elicits it, and then with a voluntary behavioral response” (Claim 6).
5. The Specification teaches that “experimental animals are trained to exhibit stimulus-recognition behavioral response. Correct recognition is reinforced by reward” (Spec. 29).
6. The Specification teaches “[t]raining animals to manifest behavioral response to external stimulus. . . . Group A is trained to exhibit behavioral response R_j to stimulus S_j; and Group B is trained to exhibit response R_k to stimulus S_k” (Spec. 31).

7. Claim 6 requires a second step of “detecting, immediately following said external stimulus and said corresponding behavioral response, brain loci that manifest transient increased activation” (Claim 6).

8. The Specification teaches that “[b]rain loci manifesting increased metabolic activity in response to the stimuli are identified by means of radioactively labeled glucose analog Prior to exposing the animals to these stimuli, radioactive 2-DG is injected into the afferent neurons The animals are sacrificed and their brains are subjected to autoradiography” (Spec. 30).

9. The Specification teaches an alternative detection method in which “[v]oltage sensitive dyes show activation gradients in the brain” (Spec. 30).

10. Claim 6 requires a third step of “identifying, among the said brain loci that manifested increased activation . . . those whose inactivation selectively eliminates said behavioral response to said external stimulus, without eliminating behavioral responses to external stimuli that induce other elements of sensation within the same submodality” (Claim 6).

11. The Specification teaches that a “brain locus identified as activated in response to the particular external stimulus is then deactivated. The inactivation technique may consist of local surgical lesion, local application of neurotoxin (in non-human primates reverse deactivation would be used, such as local application of lidocaine)” (Spec. 31).

12. The Specification teaches a post deactivation test in which “[g]roup A mice, with brain loci deactivation . . . are then presented with external stimulus Sj, that normally is followed in them by behavioral

response Rj. Lj is the brain locus whose inactivation selectively abolishes behavioral response Rj” (Spec. 31).

Principles of Law

It is the Examiner's “initial burden [to] present [] evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.” *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976).

To satisfy the written description requirement, the inventor must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). “One shows that one is ‘in possession’ of *the invention* by describing the *invention*, with all its claimed limitations.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

“Although [the inventor] does not have to describe exactly the subject matter claimed ... the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

Analysis

While the Examiner is correct that the specific language of the claims was not disclosed *ipsis verbis* in the Specification (Ans. 4-5), *ipsis verbis* support is not required. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996).

The Examiner finds that “the cited pages in the [S]pecification do not disclose a step of establishing correspondence in the context of the claimed method. Rather, the cited pages appear to be discussing the state of the prior art” (Ans. 4). However, the discussion of the prior art is part of the Specification, and can be relied upon for descriptive support. More importantly, the process of claim 6 is discussed in detail at pages 29-31 of the Specification, which detail each of the steps of claim 6 as performed in mice and other experimental animals (FF 1-12).

We are not persuaded by the Examiner’s argument that the example at page 29 does not “describe an immediate detection of brain loci after performing step 1” (Ans. 5). The reasonable understanding of methods with steps numbered P1, P2, P3, etc., is sequential performance of the steps (*see* Spec. 29-30). Further, the discussion at page 30 of the Specification in which animals are pretreated with a radioactive metabolite, then subjected to a stimulus, and then sacrificed to identify the brain loci is reasonably understood as occurring after establishing the correspondence found in step 1 (FF 1-3, 8). We note that Appellant’s Specification also provides non-destructive methods to detect specific regions of interest (*See, e.g.*, Spec. 30, step P4).

We also are not persuaded by the Examiner’s argument that “[n]one of these citations disclose step 3 of the instant claim” (Ans. 6). The Specification reasonably details, prospectively, the method of inactivation (FF 10-12). While the Examiner is correct that there is not a working example in which the Appellant actually identifies a brain loci which functions to selectively eliminate a behavioral response, the Specification

teaches the step of identification of Lj, where “Lj is the brain locus whose inactivation selectively abolishes behavioral response Rj” (Spec. 31; FF 12).

We also do not find persuasive the Examiner’s argument that “the [S]pecification does not disclose the recited method in context with the other method steps” (Ans. 6). The Specification at pages 29-31 details the method in specific order, with the order of steps matching those of claim 6 (FF 1-12).

Conclusion of Law

The Examiner erred in finding that the disclosure of the Specification failed to demonstrate possession and descriptive support for steps 1-3 of claim 6.

B. 35 U.S.C. § 112, first paragraph - enablement requirement

The Examiner finds that

undue experimentation would be required because the brain is a complex organ where different species have different types of responses to external stimulus. Thus, it would require undue experimentation to determine the actual steps for identifying brain loci and deactivating brain loci to eliminate a particular behavior without eliminating other behavior responses to external stimuli.

(Ans. 8).

Appellant “respectfully submits that claim 6 is fully enabled by the present [S]pecification and respectfully requests that the rejection under 35 USC 112 be withdrawn” (App. Br. 12).

In view of these conflicting positions, we frame the enablement issue before us as follows:

Did the Examiner err in finding that it would have required undue experimentation to perform the method of claim 6?

Findings of Fact

Breadth of the Claims

13. The Examiner finds that “the instant claim is not limited to mice. The brain is a complex organ where different species have different types of responses to external stimulus. . . . The specification does not teach how the tests for mice . . . are to be modified to apply those tests to other species” (Ans. 10).

Presence of Working Examples

14. The Examiner finds that “the [S]pecification does disclose work done on mice. However, as explained above, this example does not describe the method steps as claimed or in context with each other” (Ans. 8).

Amount of Direction or Guidance Presented

15. The Specification teaches “[m]ethods of identifying brain loci L in experimental animal” (Spec. 29).

16. The Specification teaches guidelines for selecting the animals to be used for the specific neural correlates, specifically teaching that

In identifying the correlates of innate fear, for example, conditioned fear cues should be minimized, and the stimulus employed should evoke an innate response, such as abrupt loud noise or smell of cats. If the goal is to identify the correlates of basic taste, then exposure of newborn mice should be limited to one basic taste, and information about other tastes blocked.

(Spec. 29.)

17. After selection of the animals, the Specification teaches that “[a]n identical strain of mice is partitioned into two groups: Group A and Group B (depending on available facilities, a larger number of groups may be used). Each group is then subjected to different external stimuli. The different stimuli are within the *same* sensory submodality” (Spec. 29).

18. The Specification teaches several modes of “[i]dentifying *activated brain loci*” which were activated by the external stimulus (Spec. 30), including “[b]rain loci manifesting increased metabolic activity in response to the stimuli are identified by means of radioactively labeled glucose analog” (Spec. 30).

19. The Specification teaches another mode where “[v]oltage sensitive dyes show activation gradients in the brain. This technique would be used in experimental animals such as the monkey for identification of K1 proteins for functions not found in the mouse, such as color vision” (Spec. 30).

20. The Specification then teaches “[i]dentifying *brain locus whose inactivation selectively abolishes response R*” where a “brain locus identified as activated in response to the particular external stimulus is then deactivated. The inactivation technique may consist of local surgical lesion, local application of neurotoxin . . . [or] reversible deactivation would be used, such as local application of lidocaine” (Spec. 31).

21. The Specification teaches testing for deactivation where Group A mice, with brain loci deactivation in stage 05.2, are then presented with the external stimulus S_j, that normally is followed in them by behavioral response R_j. L_j is that brain locus whose inactivation selectively abolishes behavioral response R_j. Animals in Group B are then subjected to

external stimulus Sk. Rk is that brain locus whose deactivation selectively abolishes behavioral response Rk.

(Spec. 31.)

State of the Art and Unpredictability of the Art

22. The Examiner finds that “[b]ecause the brain is a complex organ that is not fully understood, determining loci of the brain with particular characteristics is unpredictable” (Ans. 9).

23. No evidence is cited by the Examiner in the rejection to support the conclusion of unpredictability.

Principles of Law

“In order to satisfy the enablement requirement of section 112, an applicant must describe the manner of making and using the invention ‘in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same ’35 U.S.C. § 112, para. 1.”

Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1323 (Fed. Cir. 2005).

Factors to be considered in determining whether a disclosure would require undue experimentation ... include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *See In re*

Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993) (Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure).

Analysis

The Examiner admits that “it is well known in the art to identify if a subject is experiencing a sensation in response to a external stimulus as in step 1 (e.g., asking a subject what he is tasting after giving him food) and detecting brain loci that manifest transient increased activation as in step 2 (e.g., taking brain images)” (Ans. 9). However, the Examiner contends that the skilled artisan “would not know how to identifying [sic] brain loci that manifest increased activation in response to the stimulus and whose inactivation eliminates the behaviour response to the external stimulus without eliminating the behaviour response to the to external stimuli that induce other elements of sensation within the same submodality” (Ans. 9).

We decide this case primarily based upon who has the burden of proof. The Examiner has the burden to provide reasonable basis for doubting enablement. *See In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

Based upon balancing the factors in the *Wands* analysis, we do not find the Examiner has established a prima facie case showing that undue experimentation would have been required to use the claimed invention. In particular, the Specification provides detailed prospective procedures on how to perform the claimed method (FF 15-21).

The Examiner has provided no evidence of unpredictability in identifying neural correlates, no evidence of unpredictability in identifying

brain loci with transiently increased activation and no evidence of unpredictability in correlating inactivation data with specific brain loci (FF 22-23).

While we appreciate the Examiner's concerns regarding the scope of the claim (FF 13), which is broadly applicable to any organism with a brain, with the prospective example limited to mice (FF 15-21), the rejection lacks evidence or specific scientific reasoning as to why the differences between the brains of mice and humans, primates, worms or other organisms would require different tests or unpredictable experimentation. The procedure of the Specification, in which control and test groups of animals are tested to identify the brain locus transiently activated by the external stimulus, followed by testing the effect of deactivation of the brain locus on different control and test groups (FF 15-21) is reasonably applicable to all organisms and specifically references monkeys (Spec. 30). The modes of deactivation, whether surgical or application of neurotoxin or lidocaine, are also reasonably applicable to all organisms (FF 20). Further, the Examiner's apparent position that the Specification cannot teach how to use the claimed method unless it teaches solutions to all possible species is contrary to controlling case law. *See, e.g., In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

Conclusion of Law

The Examiner erred in finding that it would have required undue experimentation to perform the method of claim 6.

SUMMARY

In summary, we reverse the rejection of claim 6 under 35 U.S.C. § 112, first paragraph, written description.

We reverse the rejection of claim 6 under 35 U.S.C. § 112, first paragraph, enablement.

REVERSED

Ssc:

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